FLAT IMPLANT, METHOD FOR ITS MANUFACTURE AND USE IN SURGERY

DESCRIPTION

The present invention relates to a flat implant, a method for its manufacture and its use in surgery.

Body organs or organ parts in the abdomen of patients can suffer from defects, which limit the organ function and cause problems for the patient. Examples of such defects are shifts or displacements of organs, as well as gaps in the tissue. They can be caused by illnesses, slackening resulting from age, muscle weakness, connective tissue weakness, congenital weakening of the abdominal viscera or inadequate cicatrization following earlier treatments.

In general an improvement can be obtained by a surgical operation, but this suffers from the disadvantage of a high recurrence rate. Thus, in modern abdominal surgery use is being increasingly made of synthetic reinforcing materials, which are implanted in the patient's abdomen. Polyester, polypropylene and polytetrafluoroethylene nets play an important part.

Although the use of such nets clearly leads to a reduction in the recurrence rate, such implants are still subject to problems as a result of possible infections, the formation of hard scar scales, displacements or fistula formation. Particularly in the hypogastric region as a result of leg movement there is a need for a supply of very elastic cicatrization for rapid healing and freedom from complaints on the part of the patient.

The problem of the invention is to make available an implant for use in surgical operations, which overcomes the difficulties of the prior art implants, which is simple and inexpensive to manufacture and which is easy to handle using standard surgical methods.

The problem is solved by a flat implant for use in surgery having a flexible fabric, which is formed from at least two substantially independently constructed textile fabric structures, which are firmly interconnected to form a composite structure over the entire surface area of the implant. Such a composite structure offers a high initial implant strength.

Preferably, the implant according to the invention has substantially all its composite components formed from monofilaments and is preferably exclusively formed from monofilaments. The use of monofilaments in implant structures is characterized, compared with multifilament yarns, by a reduced infection susceptibility, because germs do not find any colonization spaces such as occur between individual fibres.

Advantageously a monofilament can have a thickness of 10 to 500 μm, particularly 100 to 150 μm. According to an embodiment of the invention the monofilaments of the independent textile fabric structures essentially have the same thicknesses. According to another embodiment of the invention the monofilaments of the independent textile fabric structures can have different thicknesses.

According to the invention the fabric can be produced by a textile method, particularly knitting, weaving or braiding. Such procedures are known to the expert, so that a detailed description is not provided here. The invention gives preference to knitted fabrics.

Thus, in a preferred embodiment the implant is formed from knitwear, particularly knit goods. This permits a simple, inexpensive manufacture according to known, proven procedures using conventional machines and tools.

Advantageously the individual textile fabric structures can be constructed in the form of net structures, particularly

knitted net structures. Knitwear is characterized compared with other textile structures by a higher flexibility of the fabric, which is desirable for uses in medicine. In an embodiment the at least two nets can have substantially the same structure. In another preferred embodiment the at least two nets can have different structures. Differences in the structure can in particular be formed by different binding of the filamentary material in the textile fabric.

The openings or pores of the nets can have random polygonal or oval shapes. For example the net structure can be rhombic, latticed, honeycombed, circular or slot-shaped. Advantageously openings of at least one fabric structure preferably have a substantially hexagonal shape. A knitted net can e.g. have a honeycombed structure and hexagonal pores are surrounded by bridges formed from knitted monofilaments.

According to the invention the individual textile fabric structures can have a pore structure with pore sizes or opening sizes of 0.1 to 10 mm, particularly 0.5 to 5 mm. In an embodiment of the invention the pore sizes of the individual textile fabric structures can be substantially identical. In another preferred embodiment of the invention the pore sizes of the individual textile fabric structures can differ.

According to an embodiment of the invention the individual textile fabric structures can be produced according to the same procedure. According to a further embodiment of the invention the individual textile fabric structures can be produced according to different binding procedures. For example, in a preferred embodiment, one textile fabric is formed by knitting in accordance with the satin or atlas 2-row binding method. In another preferred embodiment one textile fabric can be formed by knitting according to the tulle fillet binding method. The production of the indivi-

dual fabric structures with different binding or weave methods permits in simple manner the formation of different pore shapes and sizes.

Advantageously the textile fabric structures can be interconnected by textile methods. Particular preference is given according to the invention to the textile fabric structures being interconnected by knitting. In this way fabric structures produced by knitting can be combined to form a composite in simple manner using the same machines and procedures.

According to the invention the textile fabric structures, particularly net structures, can be so mutually arranged that their structure pores, particularly openings do not align and in particular roughly overlap by half. The implant according to the invention can be characterized in that the textile fabric structures, particularly net structures, overlap in both dimensions of the net planes. In this way, for the same weight per unit area, a fabric which is tighter with respect to the passage of substances such as body fluids, cells or microorganisms is obtained than when the net pores are oriented in aligned manner. In addition, a closemesh textile structure facilitates the growing of the implant into the body and consequently aids rapid healing.

In the case of knitting, such net structures can be produced in that two independent fabrics are constructed on mutually laterally displaced needles. In an embodiment fabrics can be produced with different mean sizes. In this way e.g. in the internal pore size of a coarser meshed net can be located several meshes of a finer meshed net. With particular advantage such overlapping structures can be produced by the simultaneous knitting with different knitting constructions or bonds.

The implant according to the invention can advantageously be characterized in that it is at least partly absorbable in vivo. The decomposition or degradation of a bioabsorbable polymer takes place by metabolic processes in the body of an animal or human. Body and tissue fluids participate in the reaction. As a result of hydrolysis the polymer chain is split into smaller and more easily soluble fragments. The fragments are further degraded, optionally accompanied by the participation of enzymatic processes. The degradation products are transported away by the metabolic system and are eliminated from the organism in the same way as other metabolic waste products. It is important for a good compatibility of the absorbable implant material by the patient, that during the degradation process no harmful metabolites are formed or concentrated.

In the case of the implant according to the invention at least one of the textile fabric structures, particularly one having hexagonal openings, can be substantially formed from non-absorbable material and at least one further textile fabric structure can be substantially formed from absorbable material. The invention gives preference to an embodiment in which two independently formed fabric structures are provided, whereof one is formed from non-absorbable material and the other from absorbable material. It is also preferable according to the invention for the fabric structure of non-absorbable material to have hexagonal openings.

Advantageously absorbable filamentary material is used for joining the textile fabric structures. According to the invention the implant can contain absorbable and non-absorbable material in a ratio of 90:10 to 10:90, particularly 30:70 to 70:30 and preferably 50:50.

Within 8 to 12 weeks following the introduction of the implant according to the invention, as a result of the degrada-

tion reactions on the absorbable material in the body of the patient there is a implant strength loss. Due to biochemical degradation, there is chain splitting and weight loss with respect to resorbable components in the polymer filamentary material. This leads to a progressive deterioration of mechanical characteristics such as e.g. the strength and flexural rigidity. The implanted fabric becomes increasingly elastic, can better adapt to local circumstances in the abdomen and can perform movements made by the patient. Advantageously in the implant according to the invention the absorbable component is completely degraded in vivo after 6 to 50 weeks, particularly 8 to 12 weeks.

Advantageously as a result of the in vivo degradation of absorbable material, the pore size of the implant can be increased. In this way a stiffening by the growing in of body cells can at least be compensated by a partial degradation of the composite structure. Over a period of time there can be a cicatrization of the implant with parts of the abdomen, particularly an abdominal viscera. A resulting union of abdomen and implant contributes to the stabilization of the abdominal viscera and consequently ensures the success of the treatment.

With increasing degradation of the absorbable material, an implant weight loss occurs and this is made apparent by an increasingly open-cell structure. Following complete degradation of the absorbable component, a fabric structure of non-absorbable material is left behind. Preferably the fabric structure of non-absorbable material is formed with a hexagonal pore structure. A hexagonal structure is particularly advantageous for an implant remaining in vivo. In this way by choosing the textile structure of the individual fabric structures of the implant union of absorbable and non-absorbable material, it is possible to obtain an optimum structure for the growing in and adaptation to physiological

circumstances of the implant part left permanently in the patient's body. Preferably the components of the implant composite structure are chosen in such a way that following absorption of the biodegradable material, an implant is left in the body, whose mechanical characteristics are adapted to or restore the natural characteristics of the abdominal viscera.

In the present invention particular preference is given to an embodiment in which one fabric structure is formed from non-absorbable material and at least one further fabric structure from absorbable material and which are combined to an implant composite structure. A further advantage of the invention is the use of monofilaments for forming the textile fabric structures. Compared with the individual filaments in a multifilament, as known from the prior art, a monofilament has a greater thickness. Thicker monofilaments have a higher bending rigidity, which has an effect on the handling characteristics of a textile fabric produced therefrom. For the creaseless, stress-free insertion of implants in the abdomen of a patient, it is desirable to have reliable handling, i.e. a certain rigidity and strength of the implant in addition to flexibility. This is particularly important with strip-like implants, which are placed around organs, such as e.g. incontinence belts. Through the use of absorbable monofilaments in an implant composite structure according to the invention, such a desired stability is obtained.

During the biochemical resorption of the degradable components the mechanical strength and rigidity of the hernia implant continuously decrease, i.e. the implant becomes more flexible, so that the patient is less stressed by the implant. Following the degradation of the absorbable material fraction, a flexible net with only a small amount of foreign material remains in the patient's body.

In a special embodiment the monofilament of absorbable material can be thicker than the monofilament of non-absorbable materials. According to the invention preference is given to an absorbable monofilament with a thickness of 100 to 250 μm. According to the invention, preference is given to a non-absorbable monofilament with a thickness of 100 to 250 μm. This makes it possible to minimize the foreign material quantity left behind following absorption of the biodegradable material. The absorbable and non-absorbable monofilaments can have the same or different thicknesses.

According to the invention the non-absorbable material can have a weight per unit area of up to 50 g/m , particularly up to 40 g/m . The non-absorbable material can have a strength of 16 to 50 N/cm. The implant according to the invention can have a bursting pressure of 100 to 300 kPa. The implant according to the invention can have a bursting elongation or extension of 20 to 50 mm.

Advantageously the implant according to the invention is characterized in that its extensibility, measured in the longitudinal, transverse and diagonal directions, differs by no more than 50% in each case and in particular have substantially identical values. The implant according to the invention can also be characterized in that its tearing or tensile strength, measured in the longitudinal, transverse and diagonal directions, in each case differ by no more than 50% and in particular have substantially identical values.

In the case of the implant according to the invention the non-absorbable material can be selected from the group comprising polypropylene, polytetrafluoroethylene, polytetrafluoroethylene-hexafluoropropylene copolymer, polyethylene terephthalate, polybutylene terephthalate, as well as their mixtures, copolymers and terpolymers. In a preferred embodiment of the invention the absorbable material is formed from

monofilament polylactide fibres. In another preferred embodiment of the invention the absorbable material can be formed from monofilament fibres of polylactide-glycolide copolymer.

In the case of the implant according to the invention the absorbable material can be selected from the group comprising polyglycolide, polylactide, polydioxanone, polyhydroxybutyric acid, polycaprolactone, polytrimethylene carbonate, polytetramethylene carbonate, as well as their mixtures, copolymers and terpolymers. In a preferred embodiment of the invention the non-absorbable material is formed from monofilament polypropylene fibres.

In a particularly preferred embodiment the implant according to the invention can be in belt form.

According to a further development the implant can contain an antimicrobiotic agent, such as e.g. an antibiotic. The administration of antibiotics more particularly serves to prevent infections. For prophylaxis and therapy with antibiotics use is made in the surgery field of e.g. cephalosporins such as cephazolin and cephamandol, netilmycin, penicillins such as oxacillin or mezlocillin, tetracycline, metronidazole or aminoglycosides such as gentamycin or neomycin, as well as e.g. rifampicin. In accordance with the given requirements, the experts can select one or more appropriate active agents. The implant can also contain growth factors.

The present invention also relates to a method for the manufacture of an implant for use in surgery comprising the formation of at least two independent textile fabric structures and the joining together of these textile fabric structures over their entire surface area in order to form a composite structure in the form of a flexible fabric. Preferably the textile fabric structures are in the form of knit-

wear and are particularly produced by knitting. The textile fabric structures can, according to the invention, be joined by textile procedures, particularly by knitting during their joint manufacture.

For use in surgery, the implant modified according to the invention can be appropriately sterilized. An appropriate sterilization process can be constituted by conventional physical or chemical methods for inactivating microorganisms or a combination thereof. One possible sterilization process comprises treatment with ionizing radiation such as e.g. irradiation with gamma or beta rays in the range 0.1 to 10 mrad, particularly 0.8 to 2.5 mrad.

The invention also relates to the use of an implant in surgery, particularly for treating defects in body cavities, particularly for supporting and holding body organs. A preferred example for such an application is the use of a strip-like implant according to the invention as an incontinence belt. The implant according to the invention can be used as a urinary incontinence belt for supporting the female urethra.

To this end the implant material modified according to the invention can be cut to a desired size and shape. Advantageously the surgical implant according to the invention can be appropriately packed with suitable dimensions cut to size in ready to use form. Practical preferred dimensions are 2 to 5 x 30 to 50 cm for strip-like implants or 30 to 50 x 30 to 50 cm for large-area implants.

For illustration purposes embodiments of the invention are shown in exemplified manner in the attached drawings.

Figs. 1a and 1b show the front/back of a knitted fabric structure of non-absorbable polypropylene in rhombic form.

Figs. 2a and 2b show the front/back of a partly absorbable implant of non-absorbable polypropylene (PP), as shown in fig. 1, and a fabric structure of absorbable polylactide (PLLA) in rhombic form knitted therewith. The PLLA knitted fabric overlaps the pore structure of the PP knitted fabric.

Fig. 3 shows a PP knitted fabric with a hexagonal structure.

Figs. 4a and 4b show the front/back of a partly absorbable implant of non-absorbable PP, as shown in fig. 3, and a honeycombed absorbable PLLA fabric structure knitted therewith.

Figs. 5a and 5b show the front/back of a knitted fabric structure of non-absorbable polypropylene with an elongated honeycombed structure.

Figs. 6a and 6b show the front/back of a partly absorbable implant of non-absorbable PP, as shown in fig. 5, and an absorbable PLLA fabric structure with an elongated honeycomb structure knitted therewith.

Figs. 7a and 7b show the front/back of a knitted fabric structure of non-absorbable, latticed polypropylene. The longitudinally directed strands in the drawings are formed from knitted threads and the cross-connections in the lattice are formed from monofilaments.

Figs. 8a and 8b show the front/back of a partly absorbable implant of non-absorbable PP, as shown in fig. 7, and an absorbable PLLA fabric structure knitted thereto. An absorbable fine structure is superimposed on a bearing coarse structure.

Further features of the invention can be gathered from the following description of a preferred embodiment. The individual features of the invention claimed in the subclaims can in each case be implemented singly or in the form of subcombinations in an embodiment of the invention. The following example serves for illustration purposes and is not to be understood as a restriction. Modifications and changes apparent to the expert are possible without leaving the scope of the invention.

Example

Monofilaments of polylactide (PLLA) and polypropylene (PP) are processed on a warp knitting machine for manufacturing a composite net of absorbable and non-absorbable biocompatible polymer material. The satin or atlas 2-row method is used for the absorbable PLLA fabric, for which the warp arrangement is: 2-0/4-6/8-10/6-4/2-0/4-6/8-10/6-4, so that this guide bar works on needles 2, 4, 6, 8, 10 etc. For the non-absorbable PP fabric working takes place according to the tulle fillet procedure, where the warp arrangement is one guide bar 2-0/4-6/2-0/4-6/8-10/6-4/8-10/6-4, and second guide bar 8-10/6-4/8-10/6-4/2-0/4-6/2-0/4-6, so that both guide bars work on needles 1, 3, 5, 7, 9 etc. The atlas 2-row and tulle fillet are not worked on the same needles, but are instead laterally displaced by one needle. Thus, the absorbable knitted fabric forms a mesh structure with smaller pore sizes compared with the mesh structure of the non-absorbable knitted fabric. Between each of the bridges of the honeycomb structure of non-absorbable material are in each case located several meshes of absorbable material. The two knitted fabrics are interconnected by underlaps. Underlapping in vivo permits a degradation of the absorbable knitted fabric without interacting with the non-absorbable knitted fabric.

The composite net can be manufactured in large-area form and cut to the desired size. Strips with a length of 30 to 50 cm and a width of 2 to 5 cm are suitable for a urinary incontinence belt.